Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	§	MDL NO. 2326
THIS DOCUMENT RELATES TO:	§	
ALL WAVE 4 CASES IN MDL NO. 2326	§	

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Thursday, August 16, 2018

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Videotaped deposition of JIMMY W. MAYS, Ph.D., held at the JW Marriott Marco Island Beach Resort, 400 South Collier Boulevard, Marco Island, Florida, commencing at 9:08 a.m., on the above date, before Susan D. Wasilewski, Registered Professional Reporter, Certified Realtime Reporter, Certified Realtime Captioner, Certified Manager of Reporting Services, Florida Professional Reporter, Certified Court Reporter (New Jersey), and Realtime Systems Administrator

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I N D E X

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E X H I B I T S

(Attached to transcript)

E X H I B I T S

(Attached to transcript)

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THE VIDEOGRAPHER: We are now on the record. My name is Luana Pruitt. I am your videographer for Golkow Litigation Services. This deposition is being held in Marco Island, Florida, in the matter of Boston Scientific Corp. Pelvic Repair Systems Product Liability Litigation to be heard before the United States District Court for the Southern District of West Virginia.

Our deponent today is Jim Mays, Ph.D.

Will counsel please introduce themselves beginning with plaintiff counsel.

MR. PERDUE: This is Jim Perdue, Jr., on behalf of the Plaintiffs in the MDL.

MS. STEELE: And this is Andrea Steele on behalf of the Defendant, Boston Scientific.

THE VIDEOGRAPHER: And will our court reporter, Susan Wasilewski, please swear our witness?

THE COURT REPORTER: Do you solemnly swear or affirm the testimony you're about to give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do.

THE COURT REPORTER: Thank you.

JIMMY W. MAYS, Ph.D., called as a witness by the Defendant, having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. STEELE:

Q. Good morning, Dr. Mays.

A. Good morning.

(Mays Exhibit 1 was marked for identification.)

BY MS. STEELE:

Q. I'm going to hand you what's been marked as Exhibit 1, which is the notice to your deposition. Have you seen this document before?

A. Yes, I have.

Q. And if you turn to page 3, pages 3 and 4 are 14 document requests in Exhibit A, and Counsel handed me before the deposition a folder of documents that you brought responsive to these requests. Is that right?

A. Yes.

Q. And the first document is a copy of your report that you served?

A. Correct.

Q. We'll mark -- and then you also brought a copy of your curriculum vitae?

A. I did. That's the most up-to-date.

Q. Most up-to-date. And do you think there were changes since you served your report in June?

A. They would have been extremely minor.

MS. STEELE: I'm going to go ahead and mark the report, along with the updated CV, as Exhibit 11 for the record.

(Mays Exhibit 11 was marked for identification.)

(Mays Exhibit 12 was marked for identification.)

BY MS. STEELE:

Q. And then Exhibit 12, I'm going to mark the -- and this is an invoice from June 7th, 2018, to Clark, Love & Hutson.

A. Correct.

Q. And this is for consulting work that you did on what is basically an update to your general report in this litigation. Is that accurate?

A. Yes, it is.

Q. And it looks like you -- for specifically for -- we call this Wave 4. Do you under -- so if I use the term "Wave 4," do you understand?

A. Generally, yes. I don't know the specific

details but I understand that it has come in waves.

Q. Yes. So, generally, you understand that you've served two other general expert reports in the MDL before?

A. Yes, I did.

Q. And you served a third expert report that updates certain sections in June of 2018, right?

A. Yes.

Q. And this invoice pertains in particular to the updates that you made to the report that you served in June?

A. Yes. Correct.

Q. And it looks like between May 14th, 2018, to June 7, 2018, you spent 14 hours preparing your updated report; is that right?

A. Yes.

Q. And so that your total invoice for updating your report in the Boston Scientific MDL comes to $4,900; is that right?

A. That sounds right, yes.

Q. And have you performed any work related to the Boston Scientific litigation since June 7th of 2018?

A. Only some preparation for this deposition today.

Q. And approximately how much time have you spent preparing for your deposition today?

A. Oh, this is a guess. I probably spent about maybe 10 or 12 hours reviewing my prior depositions, reviewing my report, looking at some documents that I thought were relevant, and then I spent a couple of hours with Mr. Perdue yesterday in preparation as well, so maybe a total, I'm guessing, maybe 14 hours.

Q. And when you were reviewing your prior deposition testimony, was there any testimony that you reviewed that was inaccurate or your opinion has changed since you gave that testimony?

A. You know, I saw a couple of little things but they are very minor. I think I referred to Dr. Thames' extensive way of treating the explants to remove tissue as a 16-step procedure in the depo we had prior, but it's really a 23-step procedure. I don't know how I got 16 in my head, but -- I noticed that but, otherwise, I noticed a typo or two but nothing of any substance.

Q. Okay. And when you reviewed your prior reports, and I have them with, so I can mark them for you, too, were there any opinions stated in your two prior expert reports in the Boston Scientific

MDL that have changed?

A. No.

Q. And in May of 2018, when you started working on your updated report, how did that come to be that you decided to update it?

A. I was contacted by Ms. Hutson, Shelley Hutson, and she asked if I would prepare an update for this new wave of cases.

Q. And can you describe the steps you took after your conversation with Ms. Hutson to update your report?

A. Yes. I went back and reviewed my prior reports, I reviewed our paper published in Biomaterials that contained our own testing data, I did some literature searches to find new papers that were out there where people investigated explanted polypropylene, and that's really the start of gathering the pertinent information and then making the revisions.

Q. Did you conduct any further testing?

A. No.

Q. Since you were last deposed in a Boston Scientific case, which you were deposed in December 2016 by myself and then you were deposed again in another state court case in January 2017?

A. That sounds right, yes.

Q. And since that time have you performed any testing on polypropylene mesh?

A. Not on polypropylene pelvic mesh.

Q. Have you performed any testing on any polypropylene surgical mesh for any application?

MR. PERDUE: Well, so in -- do you want to know about Boston Scientific or just polypropylene in general?

MS. STEELE: Polypropylene in general.

MR. PERDUE: So I need to invoke a privilege that's not his because it's my understanding that he has been engaged as a consultant in looking at some other meshes, but I can put on the record, Andrea, that he hasn't been designated and he hasn't rendered a report, but it is -- it is litigation-based testing. It's work product. The attorney that retained him to look at it obviously has a privilege on that. I have no idea where it is, but I asked him have you been disclosed, have you written a report, and he has not.

So I need to invoke that lawyer's privilege, but if it goes further, I will supplement as necessary under the rules. I will represent to

that on the record. Okay?

BY MS. STEELE:

Q. So you have been engaged in litigant -- further litigation consulting and you're palming testing, but at this time that testing has not been disclosed or put into an expert report; is that right?

A. That's correct, yes.

Q. Have you performed any nonlitigation testing of any polypropylene mesh since your last Boston Scientific deposition?

A. No.

MS. STEELE: And I'll go ahead and mark the invoice as 12.

Q. When you were preparing for your deposition, did you review any Boston Scientific documents?

A. No.

Q. Was your review of articles and literature?

A. Yes.

Q. In particular, the ones contained and summarized in your report?

A. Yes.

Q. Did you review any additional articles regarding the topics within your report that weren't include -- cited within your report?

A. You know, I'm -- as a polymer chemist, I'm continually reviewing the literature and I see papers on polypropylene, I see papers on different things, but I would say, really, that there is nothing that falls specifically in the category of this litigation that comes to mind.

Q. So, basically, there is no new literature that you've seen on, you know, testing of explanted transvaginal mesh that isn't in your report but you reviewed it since you wrote your report?

A. That's correct. I've -- yeah, I've included everything in my report that I was aware of at that time, and I'm not aware of anything that's really substantial that's been published since then, although I will continue to monitor the literature.

(Mays Exhibit 13 was marked for identification.)

BY MS. STEELE:

Q. And then I want to mark as Exhibit 13 -- and can you describe what Exhibit 13 is?

A. Yes. I was invited to give a plenary lecture at a GPC conference, it was called GPC2017, in June or July of last year, it was July 19th of last year, and I gave a presentation on the use of high temperature GPC to characterize in vivo

oxidative degradation of polypropylene.

MS. STEELE: And I'm going to ahead and mark that Exhibit 13 and we'll probably come back to that once I have time to review.

BY MS. STEELE:

Q. Do you have any further documents in your possession that are responsive to Exhibit A that aren't contained within the report, including the reliance list, the CV, your invoice, and then the PowerPoint that haven't previously been produced to Boston Scientific?

A. No, I think you have everything here, yeah.

(Mays Exhibit 2 was marked for identification.)

BY MS. STEELE:

Q. I hand you what's been marked as Exhibit 2 and Exhibit 2 is -- do you recognize this as the initial report that you gave in the Boston Scientific litigation coauthored with Dr. Samuel Gido?

A. Yes, I did.

Q. And this was originally written and served in 2013?

A. I believe that's correct. Let me look at the signature date. Yes, it was signed on

December 5th of 2013.

(Mays Exhibit 3 was marked for identification.)

BY MS. STEELE:

Q. And then Exhibit 3, and do you recognize Exhibit 3 as the solo-authored expert report that was previously served in Boston Scientific's MDL in 2014?

A. Give me just a moment. Yes, I believe this to be that report.

Q. And none of the opinions contained within this report have changed or become invalid since you wrote it, they've just been supplemented by additional literature?

A. That's correct, yes.

Q. And both of those reports contain testing that you or Dr. Gido had conducted for purposes of this litigation; is that correct?

A. Yes. Both Dr. Gido and I had conducted experimentation that went into this first report. Now, the second report certainly contains experimental data from my laboratory.

Q. So just -- your second report only contains testing that you conducted and at that time Dr. Gido was no longer involved in the litigation, correct?

A. I only see my data in this second report and I really am not sure of the answer to your second question about whether Dr. Gido was still involved in some way or not.

Q. Okay. That's fine, yeah.

A. But he was not involved in this.

Q. In your authoring of the report?

A. Yes.

(Mays Exhibit 4 was marked for identification.)

BY MS. STEELE:

Q. I hand you what's Exhibit 4. And is Exhibit 4 the report that we received in June of 2018?

A. Yes, this -- this is it.

Q. And this contains your most current opinions regarding polypropylene mesh and oxidative degradation?

A. That's correct. It's mainly updated to include some references that have more recently appeared.

Q. And the extra report that's been marked as Exhibit 4 does not contain the data from any of the testing that you had previously conducted in the Boston Scientific litigation, correct?

A. Actually, the data were not included in this report because we had published the data in a peer-reviewed paper, so I include reference to that peer-reviewed paper and the supplementary information that's available with it and I proceed to discuss the key findings of that paper in this report, but it seemed unnecessary now that the data is out there in the peer-reviewed literature to include it directly in the report.

Q. Okay. And keep that one close.

MS. STEELE: Do you need copies of anything, Jim?

MR. PERDUE: I'm listening.

MS. STEELE: You're listening. I'm sure you have plenty of copies of all of it.

(Mays Exhibit 5 was marked for identification.)

BY MS. STEELE:

Q. I'm going to hand you what I've marked as Exhibit 5, and these are the exhibits to the expert report from June of 2018, and I'll represent to you this is what was attached to your report. And there is three exhibits, Exhibit A, B and C, and the first exhibit, A, is your curriculum vitae. Is that correct?

A. That's correct.

Q. And then if you turn, and it's quite a few pages back due to your extensive career --

A. I'm getting old.

Q. Exhibit B.

A. Yes, I see it.

Q. And this is a list of documents reviewed by you in the litigation; is that correct?

A. That is correct.

Q. And did you actively update this -- the Exhibit B when you were preparing your report or coordinate with counsel to update?

A. Yeah. I was asked by counsel to provide any new references, any new information upon which I was relying, and I did so.

Q. And did you ask for any additional documents from counsel when you were preparing the report that was marked as Exhibit 4, your most up-to-date report?

A. No.

Q. Have you conducted any additional Internet research regarding Boston Scientific or any of the issues in the litigation?

MR. PERDUE: Objection to form. That may be overbroad.

A. I really have not. Certainly, you know, after I testified in some trials, I knew that there was information out there and I was curious to see what might be on the Internet about my testimony in those trials, so I looked at that, but that's been some years ago now, but I don't routinely follow, you know, Boston Scientific stock or details like --

Q. No Google alerts?

A. No, no Google alerts.

Q. And then Exhibit C is the -- your testimonial history and your compensation structure; is that right?

A. Yes.

Q. And are you still being compensated at the rate of $550 per hour for deposition or courtroom testimony?

A. Yes, I am.

Q. And are you still being compensated at the rate of $350 per hour for other work?

A. Yes.

Q. Do you have an estimate of the total compensation you've received in the Boston Scientific mesh litigation?

A. I don't. It's gone on for several years now, obviously, around four to five years, and I've

done a lot of work in the case, so it's substantial. I would say it's hundreds of thousands of dollars, perhaps.

Q. Would you estimate it above or below $500,000?

A. I would estimate it as below $500,000 but probably above $100,000, just a ballpark.

Q. And you've also offered expert testimony against other manufacturers of mesh medical devices?

A. I have been deposed in matters involved Ethicon and AMS, as well as, obviously, Boston Scientific.

Q. Have you ever offered any expert report or deposition testimony against Bard, CR Bard?

A. I have not.

Q. And for Ethicon and AMS, as far as your total compensation, is it in the same ballpark for each manufacturer as you gave me for Boston Scientific, or would it be --

A. Boston Scientific is definitely the most because I've been involved for the longest. I testified in three trials there. This is my fifth deposition in that case.

With Ethicon, considerably less; and then with AMS, even less than that.

Q. For Ethicon, would you estimate under $100,000, or above?

A. I was deposed twice. I wrote a report. I would say under $100,000.

Q. And AMS, I'm assuming, is much less?

A. Yes, it's much less. If you want a guess there, I would say maybe, I don't know, $20,000, something like that. Please don't hold me firmly to those numbers.

Q. Yes.

A. I'm just trying to give you my best estimate as I sit here without my billing documents in front of me. I could always go back and review and give you more specific information if needed.

Q. Okay. Thank you.

And then there is a list of your recent trial testimony for the past four years, and that's the last page of the Exhibit C, and I see Integra Life Sciences Corp., vs. Hyperbranch. Was that a patent case?

A. That was indeed a patent case.

Q. Did it involve polypropylene?

A. It did not.

Q. And then there are three trials and those are all against Boston Scientific; is that correct?

A. That's correct.

Q. And is there any other trial testimony that you've given in the past four years that's not on this list?

A. No. I've certainly given additional trial testimony in other cases, but I think that was all in the more distant past, more than four years ago.

Q. Besides the pelvic mesh litigation and then the other litigation that we've discussed you haven't been disclosed in, are there any other litigations that you are actively consulting with attorneys on?

A. Yeah. You know, I've done a fair bit of expert witness work over the past 30 years. I've done some work now and then dealing with polyisobutylene sealants that are used in insulating glass units. I've been told that that's not completely over, that it may resurface, but, yeah, the main things I've been involved with recently are mesh and this Integra Life Sciences vs. Hyperbranch Medical Technology. That is a patent dispute over surgical sealants that are used to seal wounds after cranial or spinal surgeries.

Q. Okay. You can set that to the side.

And, Dr. May, since the last time you were

deposed, you have now retired; is that correct?

A. Yes. I retired at the end of 2017. I'm now professor emeritus at the university. I don't get paid for that. The big thing about it is I retain library privileges, and that's so helpful to me, to still be able to access the University of Tennessee library.

Q. Do you have any active teaching or research duties or obligations?

A. No. My last graduate student finished in April. She defended her dissertation in April and actually graduated in May, and I went back to the university for that. She was my last student, so my research operation is completely shut down there now, and no teaching responsibilities either. Retired life on Marco Island.

Q. Yes. Very good. And in preparing your report that was marked as Exhibit 4, did you consider any information specific to any plaintiff in this Boston Scientific MDL?

A. Not in preparing this updated report.

Q. And let's go through some of the -- what I noted were additions, small or larger, in your report.

A. Okay.

Q. I wanted to first turn to page 14, and on page 14 generally, you can scan it, but this page deals with the specific grade of polypropylene that's used in Boston Scientific's pelvic mesh devices; is that right?

A. Yes. It discusses the Marlex HGX-030-01 polypropylene.

Q. And it contains mostly a discussion of the antioxidants used in that polypropylene; is that right?

A. Yes. There is a paragraph here that describes some antioxidants, Irgonox and Irgofos, that are in those materials.

Q. And the specific sentence that I want to look at is the first full paragraph, the second sentence that states: The MSDS sheets for these materials state that they are not intended for use in products for which prolonged contact with mucous membranes, body fluids, or abraded skin or implantation within the human body is specifically intended, unless the finished product has been tested in accordance with nationally and internationally applicable safety testing requirements.

And what opinions are you offering regarding

the safety of using Irgonox and Irgofos in a polypropylene mesh for permanent implant in the human body?

A. Simply that the manufacturer is cautioning that they can have some toxicity associated with them and that they shouldn't be used in permanently implanted products like mesh.

Q. Unless the finished product has been tested in accordance with nationally and internationally applicable safety testing requirements?

A. Yes.

Q. Is that correct?

A. That's correct.

Q. Were the Boston Scientific pelvic mesh devices, the finished products, tested in accordance with nationally and internationally applicable safety testing requirements?

A. They certainly went through some testing, some biocompatibility testing, but they never, as far as I've been able to ascertain, went through clinical trial testing.

Q. Premarket?

A. Yes.

Q. Have you reviewed clinical trials postmarket?

A. I have reviewed a lot of data on these materials. I don't think I have actually reviewed what is officially considered a clinical trial of the material. Maybe I missed it.

Q. Could you just say -- can you -- a definition of what you mean technically considered a clinical trial?

A. To me a clinical trial is something that you do before you introduce a material into the marketplace.

Q. Okay. Are you offering an opinion about whether or not the antioxidants Irgonox and Irgofos are toxic if implanted permanently through a finished polypropylene device?

A. I'm offering the opinion that they could be and that the manufacturer thinks that there is some cause for concern and that some testing is required.

Q. Are you offering an opinion as to what testing is required?

A. No, I'm not.

Q. Are you offering an opinion as to whether or not Boston Scientific completed the required testing to demonstrate that the use of the antioxidants Irgonox and Irgofos are not toxic in this application?

A. They certainly did some biocompatibility testing, but long-term toxic effects that extend beyond that, I don't know that they did that.

Q. And you're not offering the opinion that these are toxic antioxidants, just that they could be and testing would need to be done?

A. They could be, yes.

Q. And that is based on the statement on the MSDS sheets for those materials; is that right?

A. Yeah, and also the chemical structure of these compounds and the fact that they do undergo reaction when they are serving their function as antioxidants, and so you really need to explore thoroughly long-term both the biocompatibility of the materials themselves and also the products that are obtained when they do their job, when they react with oxidizing agents.

Q. Are there any other specific sources of literature or technical documents regarding the use of the antioxidants Irgonox and Irgofos that you're specifically relying on?

A. No, simply the MSDS sheets at this -- in this document, yes.

Q. And are those MSDS sheets publicly available?

A. Yes.

Q. So if I went on line and I found the sheets, those are the same or that's how you found the sheets?

A. There are different manufacturers that produced different MSDS sheets, but the Irgonox and Irgofos names identify those as Ciba products, so those Ciba MSDS sheets are available online.

Q. And perhaps my inartful question. You did not go directly to the manufacturer and ask for the MSDS sheets?

A. No, I didn't, although, actually, they may have sent them to me before because I've actually used these antioxidants in the course of my laboratory work, and if you order Irgonox, you will receive an MSDS sheet, so --

Q. And in what application have you used Irgonox or Irgofos?

A. Yeah, I particularly use these materials to stabilize polydienes, like polyisoprene and polybutadiene. They are also susceptible to oxidative degradation.

Q. Are those materials used for permanent implantation?

A. I'm not aware of an application where those

materials are used for permanent implantation, but I can't completely rule it out. I simply don't know, but I don't think so.

Q. In the materials you were developing or testing, were they used for a short-term, long-term, permanent implant?

A. They were not used as implants. These were elastomeric materials that are being used as such, elastomers, rubbery materials.

Q. Rubbery materials?

A. Yes.

Q. I wanted to turn now to page 21 of your 2008 expert report.

A. Okay.

Q. And specifically I want to -- so the first full paragraph which is -- starts with "My research group carried out a study..."

A. Yes.

Q. And this study -- I'll hand it to you, it's been marked as Exhibit 6.

(Mays Exhibit 6 was marked for identification.)

BY MS. STEELE:

Q. And is that a copy of the published study?

A. Yes, it is. This is the published paper.

This does not include the supplementary data, which is substantial with this, but yes, this is the main paper.

Q. And we previously discussed the details of this testing and this article in detail in a prior deposition; is that right?

A. Yes, we did.

Q. And the testing that's encompassed within the article with lead author Imel entitled "In vivo oxidative degradation of polypropylene pelvic mesh," and with you -- are you the corresponding author, is that --

A. Yes, and -- yeah, I was a corresponding author on this.

Q. And so the testing contained within this article is testing that was completed for the purposes of litigation in the Boston Scientific pelvic mesh litigation, correct?

A. Well, this contains the characterization work that was done at the University of Tennessee, and also work that was done by Sam Gido in this case. You know, we weren't asked by attorneys to do any particular test. We were given materials that were explants. I was aware of Clave's paper saying polypropylene is not inert in the human body. So I,

in collaboration with Dr. Gido, outlined a series of experiments that we thought would test what the actual cause of degradation is.

Q. And that testing is -- so, basically, there were two parts of the testing that you and Dr. Gido tested explanted mesh materials, correct?

A. Yes.

Q. And those test results are contained within your first report?

A. Yes.

Q. And then you conducted further characterization testing on polypropylene pellets as long as -- as well as pristine polypropylene meshes for Boston Scientific, right?

A. That's correct.

Q. And that testing is outlined in the data that is within your second expert report, is that -- which is marked as Exhibit 3; is that right?

A. That's correct.

Q. And the testing that's outlined in Exhibits 2 and 3, which are your two prior expert reports, are the basis for all of the data that's contained within the Imel article, correct?

A. Yes, I believe they are the basis of all of the experimental data. We did have an addendum

where we looked at the effect of bleach exposure on a pristine polypropylene mesh just to make sure that there is not oxidative degradation that is occurring due to the bleach, and we allude to that testing in here as well, so, yeah, maybe with that one additional experiment.

Q. With the one kind of control experiment using bleach on pristine mesh, there is no additional testing that -- in the Imel article that's not contained within Exhibits 2 and 3, correct?

A. I think that's correct, yes.

Q. Now I want to turn to -- we'll discuss Dr. Thames' article and the responses, but first I want to talk about on page 25. On page 25 in the first paragraph --

(Mays Exhibit 7 was marked for identification.)

BY MS. STEELE:

Q. I'm going to hand you Exhibit 7, which is an article with lead author Talley, and this article contains two components: First, an in vitro oxidative degradation test completed by Drs. Russell Dunn and Scott Guelcher. Is that right?

A. Yes. It does contain some in vitro

oxidation testing of hydrogen peroxide plus a catalyst. Who exactly conducted the experiments I can't say, but, you know, I do see the five authors that are here, so --

Q. Have you reviewed any of the test results from Dr. -- any of the five authors in a form of an expert report, or just through this article?

A. I'm not sure I understand what you're asking.

Q. So --

A. You're asking have I seen their expert reports?

Q. Have you seen their expert reports and the data as laid out in those expert reports, or have you only considered the published article?

A. I have not seen these data in any expert report, only in this published one, to the best of my understanding.

Q. Yeah. Just so I have an understanding of --

A. Yeah, yeah.

Q. -- what level of detail you have reviewed as far as the data for this article.

And as far as -- I want to -- I know they also looked at, I think especially with Dr. Iakovlev's AMS mesh explanted from a patient,

they scraped material off of and then conducted some different testing, but I want to focus on the in vitro testing that was conducted on the Boston Scientific pristine meshes.

A. Okay.

Q. And -- and they also conducted pristine in -- strike that.

They also conducted in vitro testing, the same testing on pristine Ethicon mesh, if you look at the third page of the article; is that right, where they have the -- they lay out in Table 1 the materials?

A. Yes. I see two Boston Scientific materials here and one Ethicon material.

Q. And an in vitro test is on the material that's never been implanted in the human body, correct?

A. Yeah. An in vitro test is one done basically in the lab, as opposed to in vivo, which is in the human, in the body.

Q. And if you look at the details underneath that table regarding the mechanism that they used to induce oxidation in this in vitro test method, they placed the slings into a solution that was 20 percent hydrogen peroxide and 0.1 molar cobalt

chloride; is that correct?

A. Yes, I see that. That's correct.

Q. And what was the purpose of them placing the polypropylene meshes into that solution?

A. They wanted to see the effect that the strongly oxidizing solution would have on the chemical structure of the polypropylene.

Q. And you said strong oxidizing solution?

A. Yes.

Q. And did you do any research to determine the relative strengths of the oxidizing solution versus the human body and the presence of oxidative species in the human body?

MR. PERDUE: Form.

A. I did not try to quantify, for example, try to find out if it's five times more intense than the environment in the human body versus this or not, so I haven't tried to quantify either.

Q. And as far as the in vitro test, what is your main takeaway and your opinions from the in vitro test that's laid out in the Talley article?

A. Yeah, it's exactly what I say here in my report, that very recently Iakovlev -- I always have trouble with that name -- and Guelcher published another study where in vitro treatment of

polypropylene meshes, Ethicon and Boston Scientific, for five weeks resulted in the appearance of strong bands in FTIR associated with hydroxyl groups and carbonyl groups. These peaks are strong spectroscopic evidence for in vitro oxidation of polypropylene. Pitting and meshing were observed in SEM of these materials.

So those are the main takeaways, that they did see the formation of carbonyls and hydroxyls and peroxy type groups, as well as observing pitting and the like in the fibers themselves.

Q. Does this article support your opinion that poly -- Boston Scientific's polypropylene mesh undergoes oxidative degradation in the human body?

A. This supports the fact that Boston Scientific polypropylene mesh can undergo oxidative degradation resulting in pitting and cracking and the appearance of these hydroxyl and carbonyl bands, but this is an in vitro test, not an in vivo test.

Q. So their tests demonstrates that Boston Scientific's polypropylene mesh can undergo oxidative degradation in the oxidative medium that they used, correct?

A. Yes. That's what these in vitro experiments show.

Q. The in vitro experiment -- strike that.

From the in vitro experiment you cannot conclude that Boston Scientific's polypropylene mesh will undergo oxidative degradation in the human body, correct?

A. One would be suspicious. One certainly couldn't exclude it because it's well known that the foreign body response attacks implanted objects with strong oxidizing agents, so you might expect to see a similar oxidative attack in vivo, and that's what our own testing of Boston Scientific explants shows.

Q. Before the Talley article and the in vitro test in that article, it is conclusive evidence that Boston Scientific's polypropylene mesh will undergo oxidative degradation in the human body, right?

A. I disagree strongly, because our published data was out there, and our published data was before this particular paper and it shows quite conclusively that oxidation is occurring.

Q. So if you combine your test results with the test results in the Talley article, correct?

A. Well, Talley didn't just do the in vitro testing. They also did testing of explanted material. Now, it was, admittedly, an Ethicon explant that was tested. I believe that's the case

here.

Q. Or AMS.

A. Yeah, let me see what it was. Was it AMS?

Q. I believe so.

A. I simply seem to recall that that explant was not Boston Scientific.

Q. That's correct.

A. But they find, you know, that the material is undergoing oxidative degradation, the explanted material, and it's still polypropylene, whether it's AMS's polypropylene or Boston Scientific's polypropylene. Polypropylene is polypropylene.

Q. Would you expect most polymers to undergo oxidative degradation in the solutions used in the in vitro test?

A. That's a pretty broad question. I would expect some to undergo oxidation. Polypropylene, because of its chemical structure, is particularly susceptible to oxidative degradation. If you substituted polyethylene, admittedly structurally quite similar to polypropylene, it would be much less susceptible to in vitro oxidation under the same conditions because it lacks the tertiary hydrogens that are present on polypropylene. Other polymers, like Teflon, to try

to give you a more complete answer, I wouldn't expect to see any effect of this solution on Teflon. I believe Teflon would be inert under these conditions.

Q. Okay. Have you -- did you conduct any research on polyethylene to see if in vitro testing on ultra-high weight -- molecular weight polyethylene had ever been subjected to the solution and undergone oxidation?

A. I haven't actually done this type of in vitro testing that they report here. I've never taken that 20 percent hydrogen peroxide and catalyst and put a polymer in it, but knowing what I know about the reactivity of alkanes, I know that polyethylene will react, it will undergo oxidation for sure, and in the past I've done work with polyethylene explants that were used in joint replacement surgeries, this is when I was at UAB in Birmingham, and we saw strong evidence that those materials were oxidized in vivo.

But I would just expect the polyethylene to be less susceptible to oxidation under the same conditions. It would -- for the same time of exposure to the same concentration of reagents, when you take out the polypropylene, I would expect to

see more oxidative degradation than with the polyethylene.

Q. And then I want to turn to Figure 3, which is an almost full-page figure on Page 542 at the top left corner.

A. Yes.

Q. And if we look down into the caption or description for the figure, these pictures are meant to demonstrate the different surface degradation effects on the materials?

A. Yes. These are SEM images showing the polypropylene mesh before treatment and after treatment in vitro with that peroxide solution.

Q. And the purpose of SEM is so you can observe the surface of the material to see if there has been any effect on the surface, correct?

A. Correct.

Q. And you see here that there is effects on the surface of the meshes after they've been put into the in vitro solution, right?

A. Yes.

Q. And as described by the authors who conducted the experiment, low magnification images showed the knitted monofilament structure. Medium magnification images revealed evidence of pits,

peeling, flakes and shallow craters on the surface. Correct?

A. Yes.

Q. And in the in vitro test, they do not note that there is images revealing evidence of cracking in the monofilaments, correct?

A. I'd have to go back and review this a little more carefully to be sure, but I think you're correct.

Q. So --

A. Flaking, peeling and pitting is what they say, such as flaking, pitting and peeling.

Q. And I know this isn't the best resolution copy of the photographs, but looking there, you see kind of an uneven surface -- surface topography due to the degradation effects, especially in the last row; is that correct?

A. I'm not sure what you -- what you mean by uneven.

Q. So you see pits in some areas and flakes in different areas and still almost smooth polypropylene in other areas, right?

A. I'm not sure I would say smooth in any area, but, yeah, some areas are certainly more damaged than others, I absolutely agree with you there.

Q. So the degradative process wasn't evenly around the fiber, correct?

A. Yeah, there were regions where it was more severe than others for sure.

Q. And that fits in, actually, with your general opinion regarding the amorphous structure of polypropylene in the crystalline versus noncrystalline regions; is that right?

A. Yeah, it's true, polypropylene is semi-crystalline. The amorphous regions are much more susceptible to oxidative attack because the chains aren't packed as tightly together, so the oxidizing agent can get in there. The crystalline regions are much less susceptible to oxidative degradation because they are more dense. It's harder for the oxidizing agent to get in there.

But the actual cracking and pitting could be when some amorphous regions are eroded away by the oxidative agents and then, finally, just because of gravity or because of physical agitation, a chunk of material falls out, and that could be what's resulting in some of these areas where you see pits in other regions which appear to be -- I wouldn't say smooth but less pitted.

Q. Less pitted?

A. Yes.

Q. And as far as the authors of this article, in their description of the surface degradation they do not use the word cracks, correct?

A. Again, I would have to go through and review the whole article. Can you -- you know, when I look here at the caption to Figure 3, they are saying no evidence of features associated with the surface degradation was observed, such as flaking, peeling, or pitting under the medium magnification images.

But then they go on to say that medium magnification images revealed evidence of pits, peeling and shallow craters on the surface.

Q. They do not say that there is evidence of cracking on the surface, correct?

A. Let me continue to look at it.

Some regions of the mesh showed evidence of larger scale features such as detachment of peeling flakes, but I don't specifically see the word crack here.

Q. And if you look at these images, and if you -- when you were reviewing this article, did you see photographs that had the layer of transverse cracking that you and Dr. Gido observed on the explanted meshes?

A. I'm sorry. Could you repeat that? It was kind of long.

Q. Yes. So -- I have a tendency to do that, you may notice. I try to pack too much into one question.

But, so, just looking at these images -- and if you want to refer to your article as well, you can, to look at the SEM images in your article.

So in your article, when you did SEM or Dr. Gido performed SEM, you observed transverse cracking around the polypropylene fibers, correct?

A. That's correct, on explanted materials that had been in vivo.

Q. But when they did a purposefully very strong oxidative in vitro test --

A. Yes.

Q. -- there is not evidence of transverse cracking around the polypropylene fibers, correct?

A. I don't see strong evidence of it in these images here, and I've got some thoughts on why that could be the case.

Q. And turning to the AMS or the other mesh that they -- the explanted mesh that's in this article --

A. Okay.

Q. -- which I believe is on page 454.

A. Yes.

Q. And they characterize the surface -- the surface of the polypropylene fibers recovered from mesh explanted from a single patient with -- by XPS.

And XPS tests the elemental composition on the surface of a material; is that right?

A. Yes, it -- yes, it does.

Q. And what they did in this test is they took portions of fibers from a mesh that was explanted from one patient and for half of them they scraped off material and the other half they did not scrape; is that right?

A. Yes, I believe that's correct.

Q. And after scraping they noted that the ratios of nitrogen-to-carbon and nitrogen-to-oxygen significantly decreased, right?

A. Yeah. Less nitrogen, much less nitrogen after scraping.

Q. And that's because the scraping was meant to remove the biologic material, right?

A. Exactly. These materials had never been exposed to formalin to crosslink the protein, so it would be easier to remove it by a physical act like scraping.

Q. And just based on that, you agree that formalin will crosslink protein, correct?

A. Oh, formalin will crosslink protein, yes, I agree with that.

Q. Can you scrape off fatty acids absorbed to the polypropylene?

A. Pardon?

Q. Can you scrape off fatty acids that have been absorbed by the polypropylene mesh?

A. I believe you could, yes.

Q. You could scrape them off?

A. I believe you could.

Q. And fatty acids do not contain nitrogen, correct?

A. Correct.

Q. So even if the levels of nitrogen decreased, you could still have the presence of fatty acids or other nonnitrogen containing biomaterial, correct?

A. You potentially could still have a fatty acid -- repeat your question. I want to make sure I really understand it.

Q. Okay. Even with -- so fatty acids do not contain nitrogen, right?

A. Correct.

Q. So if you -- in the sample, when you do EDS,

if you do not have nitrogen, you can still have the presence of fatty acids, correct?

A. You potentially could, but as we alluded to just a few moments ago, you would expect the scraping to also remove fatty acids. If you are taking the protein off with scraping, I'd say you're taking the fatty acids off as well.

Q. And they didn't perform any cleaning besides scraping, correct?

A. Again, I'd have to go back and review their protocol to make absolutely sure.

Q. I think it's page 448 has the protocol for the XPS of the explanted polypropylene mesh.

A. Oh, yeah. There it is. They actually did some separation using tweezers and scissors.

Q. Uh-huh.

A. So there was some separation done in that way, but other than that, it was just a physical scraping that was used to remove the tissue and any fatty acid that might have been there as well.

Q. How do you ensure that you aren't removing poly -- degraded polypropylene with the scraping?

A. Well, I think you have to be careful with how hard you scrape, because scraping can become

cutting if you do it too much. That's definitely something that one would have to be careful about.

Q. Have you ever conducted testing on an explanted material using scraping, tweezers and scissors as your cleaning mechanism?

A. I have used scissors and tweezers as part of just getting the mesh away from obvious bulk tissue, but no, I've never used the scraping of -- but then again, the materials we've had experience with, the explanted Boston Scientific meshes, were materials that had been exposed to formalin and, therefore, the protein was crosslinked on there and you would expect it to be more resistant to a scraping process.

Q. You can set that to the side. I now want to turn to -- and I'm just going to hand three exhibits to you at the same time, 8, 9 and 10.

(Mays Exhibit 8 was marked for identification.)

(Mays Exhibit 9 was marked for identification.)

(Mays Exhibit 10 was marked for identification.)

BY MS. STEELE:

Q. And Exhibit 8 is an article titled "The

myth: In vivo degradation of polypropylene-based meshes," with lead author Shelby Thames. Is that correct?

A. That's correct.

Q. The second article, Exhibit 9, is "In vivo polypropylene mesh degradation is hardly a myth," with lead author Margaret Thompson. Is that correct?

A. That's correct.

Q. And then Exhibit 10 is an article entitled -- or a letter to the editor entitled "Reply to 'In vivo polypropylene mesh degradation is hardly a myth," and that also is authored by Dr. Thames, correct?

A. Correct.

Q. And this is a series of articles, and then comments on the article and then a letter to the editor replying to the comments about the article that were published in the International Urogynecology Journal, correct?

A. That's correct.

Q. And the first article is testing completed by Dr. Thames and others regarding explanted polypropylene mesh that was manufactured by Ethicon, correct?

A. Yes.

Q. And in your 2018 report you have a discussion of this article; is that right?

A. Yes.

Q. And that's because it's recently -- it was recently published in late 2016, correct?

A. Yes.

Q. Online?

A. Published online September 2016, correct.

Q. And I just want to walk through this article and criticisms you have of this article, as well as topics within the article that you can agree from a scientific perspective are accurate, or you agree with. Okay?

A. Okay.

Q. And we already discussed one, you agree that formalin will crosslink protein.

A. Yes.

Q. And I know you have a kind of detailed discussion of it in your report, but can you give me kind of in your own words the major criticisms you have of Dr. Thames's work?

A. Yeah. Really, he proposes this very extensive cleaning protocol, a 23-step procedure, and it's extremely intense. It involves use of

bleach, it involves the use of enzymes, it involves extensive shaker ultrasonication process. It's changes in temperature. It's really a process that's so extreme that it would not only be expected to take off crosslinked proteins, but it would also be expected to take off oxidized polypropylene layers. That's really my primary criticism of it.

When one tries to clean an explanted material to see what has happened to it in vivo, one obviously wants to remove fixated flesh to get at the actual surface of the material, but one does not want to strip any material at the surface that has undergone changes in vivo, like oxidative degradation. That's not the idea of the cleaning protocol.

You want your cleaning protocol to be selective. So you can't get too severe. And in fact, Dr. Thames intentionally oxidized polypropylene, exposure to UV light in the presence of oxygen. That will oxidize polypropylene. And then when he cleaned the material, he omitted all of these ultrasonication steps. He did not use his own protocol. And he said -- and I say this in my report, that it would -- well, let me see exactly what he said.

Yeah. Dr. Thames admitted that the first six steps of his cleaning procedure, which involves bleach treatment, removes the majority of the proteins, and he says that the ultrasonic steps of Figure 1 were omitted to prevent undue physical damage and complete disintegration of the polypropylene fiber.

I mean, Thames is admitting that the ultrasonication step is extremely severe and not even necessary, yet, you know, he claims with the title of this paper that in vivo degradation of polypropylene-based mesh is a myth.

Q. So the main step in the cleaning protocol that you have concerns about is the ultrasonication?

A. That's the biggest part of it, yes, and it's not just one ultrasonication, but he's doing it several times.

Q. And I want to look -- I think we're both on it. It's Figure 2 in Dr. Thames's article, and this lays out the cleaning protocol that Dr. Thames used on the explants as well as the exemplar control, correct?

A. Yes.

Q. And what Dr. Thames did in his study was perform certain cleaning steps and then he would

conduct FTIR testing on the material to characterize the material, correct?

A. Yes.

Q. And he did that six times, correct?

A. He did what six times?

Q. He characterized the materials six times during his cleaning process, correct?

A. Yes. Yes. Yes.

Q. And do you have an opinion as to which -- where in this process you start to see oxidized polypropylene being removed?

A. I would agree basically with what Thames said in his -- in his two reports that I reference in my report, that the first six steps would do a -- quite a good job of getting crosslinked protein off the material.

Q. So after Cleaning Sequence 1; is that right?

A. Well, he --

Q. Or before -- so before cleaning, they rinse the materials and then they performed four additional steps that they called Cleaning Sequence Number 1, right?

A. Yes. I think I follow you, but he actually, in this Figure 2, he calls each step out explicitly, so there is 23 steps.

Q. Yeah. So you can see the different boxes --
A. Yes.
Q. -- are the first step, second step, and then he has seven sequences because he conducted material characterizations at certain points in the process, right?
A. Yes, I agree.
Q. So when we're talking about Dr. Thames and you agree that the first six steps are adequate to remove the crosslinked proteins, it's the first two rows which are the before cleaning rinses and then Cleaning Sequence Number 1, right?
A. Yeah. It's the first six steps there. I really don't think much happens with the first two steps that he does before his characterization. Rinsing with distilled water, soaking in distilled water, desiccation and drying, that's not going to remove a crosslinked protein.

But then when you get into the third step and to the fourth step, where he's actually using the bleach, bleach in a shaker, that is capable of removing the crosslinked protein, and that's -- that's the sort of treatment that you typically see folks working with polypropylene explants using. It's usually a bleach treatment of that sort.

Q. And it's usually a bleach treatment in a soaking fashion?

A. Yes.

Q. And we have seen a report of other people using the bleach treatment with a shaker.

A. You certainly could, you certainly could. There is nothing wrong with that. Ultrasonication, I think, is when you start getting extreme.

Q. That's when you -- that's what I wanted to kind of walk through. So we talked to you about the first two steps?

A. Yes.

Q. And then the third step is soaking it in a distilled water bath at 70 to 80 degrees Celsius?

A. Yes.

Q. Up to one day?

A. Yes.

Q. And will that step remove oxidized polypropylene?

A. No, I don't believe that will.

Q. Will the fourth step, which is using bleach in a shaker and the explants were in there from anywhere from five minutes to six and a half hours, depending on the amount of bulk tissue, will that step remove oxidized polypropylene?

A. Now, are you referring to the eighth step here in Cleaning Sequence 2?

Q. No, the fourth step in Cleaning Sequence Number 1. It's the use of bleach and a shaker for various times depending on the amount of bulk tissue.

A. Yeah. That will remove a crosslinked protein because the bleach hydrolyzes the peptide bonds, and so it breaks down the bonds that are creating this crosslinked protein network, and once you break an adequate number of those bonds down, then the material can simply be washed away.

Q. Will that fourth step, bleach in the shaker for various amount of time, remove oxidized polypropylene?

A. I don't believe it will. The bleach is quite specific to cleaving the protein bonds.

Q. And the next two steps are a distilled water rinse and a desiccation or drying. And will those steps remove oxidized polypropylene?

A. No.

Q. And then at that time Dr. Thames performed materials characterization, correct?

A. Yes, that's what it says.

Q. And then if you go to Cleaning Sequence

Number 2, is there any -- so at the beginning of each cleaning sequence we see that they soaked the explant materials in a distilled water bath at 70 to 80 degrees Celsius.

A. Yes.

Q. At any point in the cleaning process will that remove oxidized polypropylene?

A. That might if you've already exposed the material to ultrasonication. The ultrasonication which is coming in is really the key, because -- maybe I can back up a little and give you a good explanation.

When we talked about polypropylene earlier we said it's a semi-crystalline material. So it's roughly equal amounts by volume what I'll call bricks, the crystalline regions, and mortar, the amorphous regions, and really, those crystallites are being held together just like a brick wall, by that mortar that's there, the amorphous polypropylene, and what happens is when you have oxidation occurring with the polypropylene, it's specific to the amorphous regions, and so you're basically tearing down your mortar.

And then you come in with the ultrasonication and the physical forces of the

ultrasonication, I called it like a molecular earthquake in my report, it will literally shake the material apart. It will just crumble.

So ultrasonication after oxidation of the polypropylene is very effective. That's why Dr. Thames didn't do it to his intentionally oxidized polypropylene, because he knew it would take the oxidized layer off and he wanted to characterize oxidized polypropylene.

Q. Is it possible that Dr. Thames did not perform ultrasonication on the intentionally oxidized polypropylene because of the level of bulk degradation to the material versus the surface level degradation we see in explanted materials?

A. I don't buy that. I don't -- simply don't believe that's true.

Q. So just looking at the protocol, where things go wrong, in your opinion, is with the eighth step, which is a bleach soak step using a shaker and an ultrasonicator or ultrasonicator?

A. Yes, and then he proceeds to rinse the material with distilled water and put it in an ultrasonic bath again, and, you know, it goes on and on with a lot of ultrasonic treatments.

Q. And if we go to the 16th step, which is

using a proteinase K water bath solution, soak, with no ultrasonication?

A. Yes.

Q. Putting aside that they've already used ultrasonication, would a proteinase K solution alone remove oxidized polypropylene?

A. No, I don't believe it would.

Q. It's used to dissolve the enzymes, correct?

A. Yes. You can break down the polypropylene -- I'm sorry. You can break down the protein either by using the bleach, which hydrolyzes the amide bonds in the protein, or you can use an enzyme, which is also selective and will cleave those protein bonds.

Q. And what is the basis for your opinion that ultrasonication would remove a layer of oxidized polypropylene?

A. What I just described to you, the fact that oxidation breaks down the amorphous region, weakens the amorphous region in the material. And so if you then come in and apply ultrasound, the mechanical forces from the ultrasound will cause it to crumble.

Q. In a uniform fashion?

A. If you do it enough, certainly, and I think Dr. Thames is doing it plenty with these 23 steps.

I won't say that there is not some point where you could apply very gentle ultrasonication and perhaps only remove a portion of it. I haven't done any experiments.

Q. Can you cite any articles that discuss ultrasonication removing a surface layer from an explanted material?

A. Other than Dr. Thames's articles?

Q. Correct.

A. Ultrasonication is sometimes used to clean materials, but I think you have to be prudent about applying it and be thoughtful about how you're applying it, when you're applying it and what it might do. In the case of an oxidized polypropylene, I think it's just, you know, not a suitable method, and Dr. Thames admits it with oxidized polypropylene.

Q. Besides Dr. -- you understand Dr. Thames is not an expert for Boston Scientific?

A. I didn't know that for sure. I know he's been an expert for Ethicon, but I'm not sure about his involvement with other polypropylene manufacturers.

Q. Have you ever seen an expert report from Dr. Thames regarding Boston Scientific mesh?

A. No, I don't believe I have.

Q. Have you ever reviewed Dr. Spiegelberg's testing on Boston Scientific explanted meshes?

A. I have seen a couple of reports at least from Dr. Spiegelberg in the past. I haven't seen one in a while, but I do recall a couple of reports.

Q. And besides Dr. Thames' expert reports in the Ethicon litigation, are there any specific sources for your opinion that ultrasonication will remove oxidized polypropylene from the explants?

A. My extensive experience in polymer science and my understanding of the molecular structure of these materials and their susceptibilities. I really base it on my experience. I haven't tried to do an extensive literature search to back it up.

Q. Have you done an extensive search of ASTM cleaning standards to see if ultrasonication is used to clean explanted materials before surface characterization?

A. I have looked at some standards. I looked at the ASTM. I looked at ISO. I was specifically looking for a protocol for cleaning polypropylene explants, and I was not able to find one. The closest thing I found was a procedure, I believe it was ISO, that's used to clean explanted

polyethylene, and they used the bleach treatment, soaking in bleach.

So since polypropylene and polyethylene are structurally similar, and since there is an extensive history of folks studying explants using bleach to remove the tissue, that's what we chose to do.

Q. Okay. So your opinion that this ultrasonication will remove oxidized polypropylene is based on your own experience over the past 30 plus years in polymer science; is that right?

A. It's based on that. It's also based on Dr. Thames's refusing to use it, refusing to apply it to his intentionally oxidized polypropylene, and his admission that it would do physical damage to the material. He called it virtually disintegrate, which I think is an overstatement, but I do believe it would remove the oxidized layer, and so does Dr. Thames.

Q. And that's with the very first ultrasonication step?

A. Yes. I believe that with the first ultrasonication step he's using a shaker/ultrasonicator for one and a half to two hours, he's rinsing it with distilled water, and

then he's using an ultrasonic bath for an hour again, you know, something of the order of, you know, two and a half to three hours of ultrasonication after a bleach treatment, yeah, I think that's going to start to break down the oxidized polypropylene.

As I said earlier, whether that would take absolutely all of it -- all of it off at that point, I don't know. I'd have to do the experiments, but certainly Dr. Thames, in his additional steps, goes on to ultrasonicate again and again and again.

In fact, in his 21st step he's using four to 20 hours shaker/ultrasonicator, followed by yet another one hour in an ultrasonic bath. So I think after you go through the 23 steps, and Dr. Thames agrees with me, you've got all the oxidized polypropylene off, as well as the protein.

Q. What if he just used a shaker and did not use the ultrasonicator?

A. I believe a shaker would be suitable.

Q. A shaker would be suitable and would not remove the oxidized polypropylene layers?

A. Yeah. A nice gentle lab shaker I believe would be perfectly suitable to use.

Q. And --

A. And by the way, Dr. Thames agrees. I mean, he says the first six steps get the protein off, get the tissue off, and he's using a shaker.

Q. And I wanted to look at the SE -- I'm not sure if they actually are SEM. I think they are just microscopic images on page -- it's Figure 4. Light -- the light microscopy images, is that correct, at a magnification of X200?

A. That's what it says here, yes.

Q. And this shows the -- one patient's explant and it's Patient 33, and if you look at the chart of the patient information, this is a mesh that was implanted for 4.2 years and was in a formalin fixative; is that correct?

A. Let me go back and look. Patient 33, Patient 33 was Gynemesh implanted for 4.2 years and then stored for 3.7 years.

I'm sorry. So I reviewed that. Now your question was?

Q. Just that this is a patient whose mesh was implanted for 4.2 years before being explanted, right?

A. That's what it says, yes.

Q. And these are images after each of the cleaning sequences, not individual steps but the

sequences laid out in Figure 2?

A. Yeah. A is before cleaning, and then B through F are after the various cleaning steps.

Q. And at the end it looks like pristine polypropylene mesh, is that right, in Picture F in Figure 4?

A. I believe it does, yeah.

Q. And to the extent this patient's mesh was implanted for 4.2 years, it did not undergo any bulk degradation, correct?

A. I'm sorry. Could you repeat that?

Q. It didn't undergo any bulk degradation?

A. It's hard to say that just looking at it with a light microscope at 200X, and it's especially hard to say after the entire cleaning protocol is applied. I think, you know, to really see conclusively the damage that's occurred to the material, I think you need to -- higher power, higher magnification than 200X.

Q. Look at the same patient's explant. You can see Figure 8. The picture on the right side is Patient 33 once again, and this is in the image magnification at 200 on SEM.

A. Yes, I see that.

Q. And there we can see the transverse cracking

on the surface layer?

A. Yes.

Q. And that is what you observed in your explant testing that you published, correct?

A. Yeah. We observed transverse cracking on polypropylene fibers, yes, explants.

Q. And that is not what was observed by Talley, et al., in their study where they purposefully oxidized polypropylene mesh, correct?

MR. PERDUE: Form.

A. Talley on the in vitro oxidized polypropylene did not show this. They showed pitting and flaking and the like. There are a couple of reasons why the in vitro result might be different. First of all, who is to say that the in vitro conditions are as strongly oxidizing as the conditions in vivo.

Secondly, and this was relevant in a case I just testified in in Delaware, things in vivo are different from things in vitro for various reasons. In vivo is in a living, moving human being, and so the combination of the chemical changes that might be imparted by an oxidation process are then aggravated by the person physically moving around. So the movement can introduce physical forces that

cause cracking, for example, whereas when something is merely floating around in a test tube, it's got the chemicals acting on it but it does not have the mechanical forces.

So it's not surprising at all that you might not see this transverse cracking in the in vitro experiments of the paper that we looked at earlier this morning.

Q. You don't see the level of pitting, craters, on these explant images or the explant images in your study that were observed in the in vitro tests, right?

MR. PERDUE: Form.

A. Could you -- could you repeat that?

Q. In the Talley article they observed pits and crating, craters?

A. With their in vitro --

Q. In their in vitro test?

A. Yes.

Q. And in the Thames articles, as well as in your explant testing, there is no pits or craters observed, right?

A. In the Thames paper you clearly, on some of these things, can see transverse cracks.

Q. But you can't see the types of pits and

craters we saw with the in vitro test, correct?

A. No, I disagree. I think you do see pits and flaking.

Q. And it's your opinion that this cracking is happening in the human body before the mesh is explanted, right?

A. I believe that the mechanical forces that the human body exerts on the mesh, in combination with the oxidative effect that takes place, the foreign body response, I think that that combination can lead to what's commonly known as environmental stress cracking.

Q. And if you look at Figure 11, and it's at the bottom of page -- well, Figure 11, how did you rule out that what is causing the cracks is the formalin fixation hardening the surface layer of biologic material and then that causing it to crack?

A. I simply don't believe that that crosslinking of the poly -- of the protein that's on there, that crosslinking of the polypeptide is going to cause mechanical stresses on the layer underneath that would cause transverse cracking. It's more consistent with mechanical forces occurring in vivo as opposed to something that would be an artifact of the protein crosslinking.

Q. And if we look at Figure 11, these are two samples that were explanted from the same patient, right?

A. Well, let me look.

Yeah, these are two explants from Patient 56. It says the left sample was received dry, the right sample was received in fixative.

Q. So the sample on the left, by dry, that means it was never placed in formalin, correct?

A. I believe that's the case, but let me go back and see what he's actually referring to as dry. Maybe you can point me there.

Q. Let's see.

A. Yeah, I see in his materials and methods it simply says 12 explants were received dry and the remaining were received in fixative.

Q. And fixative is formalin, is what explanted materials are placed in?

A. I would believe that to be the case, but it doesn't explicitly say that here.

Q. But if we're looking at Figure 11, we have a sample that was received dry, not in fixative, whether it be formalin or a different fixative, right, on the left?

A. That's what it --

Q. And we see a -- woops. Sorry.

A. Yeah. On the left, it says that one was received dry.

Q. And the top row are light microscopy images, and then we have SEM micrographs in the bottom row for the two samples, right, just to orient?

A. Yeah. Light microscopy images are shown at magnification 200X at the top, and then at the bottom is SEM.

Q. And the example on the right was received in a fixative such as formalin, correct?

A. The sample on the right was obtained in a fixative, that's correct.

Q. And if you look at the SEM for the sample on the left, you do not see transverse cracks on the surface, correct?

A. And these are after Cleaning Sequence 1; is that correct?

Q. Following, yeah, following Cleaning Sequence 1, so no ultrasonication has occurred.

A. So his cleaning sequence -- yeah, that's what it says.

Q. So for the sample that was not placed into fixative, it was kept dry, on SEM imaging after Cleaning Sequence 1, where no ultrasonication has

been done, there's no transverse cracking on the surface, correct?

A. I don't detect any in this particular image. I can't see any in this particular image.

Q. But for the sample from the same patient that was placed into a fixative after Cleaning Sequence 1, you do see transverse cracking in the surface layer?

A. Clearly, that image does show transverse cracking.

Q. And if you look at Figure 10 at the top of that page, this has -- the furthest left image is from Patient 38. That was after Cleaning Sequence 1, right?

A. Yes.

Q. The middle is Patient 42, which is after Cleaning Sequence 5, which is the full 23-step process, and then the far right picture is of the TVT exemplar.

A. Yes.

Q. And if you look at the -- so Patient 38, which is after Cleaning Sequence 1, which is the first six steps in the cleaning process, you can look at that image and you see areas where there is a cracked surface coating, and then there is

pristine polypropylene fiber in another area, correct?

A. Yeah. After Cleaning Sequence 1, it does appear that there are some regions where there's no transverse cracking, but other regions where there are.

Q. So is it your opinion that the regions where there is no transverse cracking, there is no oxidized polypropylene or degraded polypropylene?

A. It's certainly possible that maybe shaking, depending on how vigorously you're shaking, could remove some of it. I mean, he simply says a shaker for five minutes to six and a half hours. It does appear that there could be a region on there where the oxidized polypropylene is removed.

Q. Could it be that there just is no oxidized polypropylene to be removed? How can you conclude one way or the other?

A. We have our own data that we -- that we generated. As I say, we used a combination of FTIR. We used SEM with EDS and we saw evidence of oxidation in every explanted material that we received.

We also measured molecular weights of the materials after being explanted, and the weight

average and Z-average molecular weights were decreased. Clearly, the reduction in molecular weight has to be from an oxidative process. I can think of no other means in vivo that would reduce the molecular weight of the material, and the mechanism of oxidative degradation points directly towards breaking of polypropylene chains.

Q. And without getting into the nitty-gritty of molecular weight testing, but in your molecular weight testing, your GPC, I think you had four samples that you conducted that testing on?

A. Yes. We had four samples where we had adequate amounts that we could test in triplicate.

Q. And in your results there was more of a reduction in molecular weights in explants that had shorter implant times than explants that had longer implant times, right?

A. I'd have to go back and look at it to be sure. We could go back and look at the table. As I just sit here and as you ask me that, I can't recall if there was that direct correlation or not.

Q. It's the GPC table, Exhibit 6, and this is your article, and just looking to confirm at your GPC results on Table 2 on page 141.

A. Yes, I'm looking at that.

Q. And we have -- the first two are controls from -- one from Obtryx, one from Pinnacle, correct, in the first two rows in your table?

A. That's correct.

Q. And then we see molecular weight testing completed on four explant samples, right?

A. Yes.

Q. And we see that for the one that was implanted for one year and seven months, it has the lowest molecular weight of any of the samples that you tested, right?

A. Yes, it does, and the others were more or less comparable in terms of molecular weight, and they were -- they were implanted for longer periods of time.

Q. Longer periods of time. So when you say comparable, so does 200,000 make something comparable?

A. What do you mean does 200,000 make coming comparable?

Q. So -- so the molecular weight difference, for example, between XP-3 and XP-7 is approximately 200,000 -- you probably will have to help me on the --

A. Yeah. Yeah, I would say that definitely the

648,000 Z-average molecular weight for XP-3 is lower than the 874,000 Z-average molecular weight for XP-7.

Q. And actually, the molecular weight for XP-7 is more similar to the controls than it is to XP-3, or closer in measurement?

A. Yeah. It's not as degraded. Yeah, there is no direct and linear correlation between the amount of time the material is explanted and the reduction in molecular weight that's seen.

Q. And turning back to Dr. Thames's article, so that Mr. Perdue does not -- -- let's see. So going --

MR. PERDUE: I'm just glad about you being in the homestretch. I'm enjoying that status.

Q. So we're looking at Figure 10.

A. Okay.

Q. So your opinion is that Patient 38, the transverse cracked area is oxidized polypropylene still?

A. Yes, that very much looks like oxidized polypropylene of a sample that's been in vivo.

Q. Could it be cracked biological material?

A. After Cleaning Sequence 1, he's exposed it to bleach and he's rinsed it, he's been shaking it. As Dr. Thames himself admits, the Sequence 1 removes

protein. So the protein should be gone, so what you're looking at is oxidized polypropylene.

Q. So if the protein is gone, you would expect on EDS to have no nitrogen present, correct?

A. If all the protein is gone, you would expect to see no nitrogen.

Q. And in your protocol, when you -- when Dr. Gido cleaned Sample 11 with bleach to remove biologic material, there was still trace nitrogen on EDS, right?

A. You can still find trace, yes. The cleaning procedure is not necessarily 100 percent.

Q. And similar to your results -- or did you -- have you observed physical mesh breakage in explanted materials in your testing?

A. Actually seen regions where the mesh has actually broken?

Q. Uh-huh.

A. Yes.

Q. And is it your opinion that that happened in vivo, not after explant or during explant?

A. You certainly can't rule out some occurring by the physical handling of the explant itself, but I do believe that that sort of cracking could occur in vivo because of the environmental stress cracking

issue that I mentioned earlier. The combination of oxidize the surface, create some weak points by eroding away amorphous material, and then put mechanical forces on it, that can lead to cracking and even breaking.

Q. In your table the longest explant you looked at was XP-11, which was four years and 9 months.

A. I believe that's correct. Yes, that's correct.

Q. And similarly, Patient 42 in Figure 10 in Dr. Thames's article and -- was implanted for four and a half years, if you look at his table of information.

A. Patient 42 was 4.5 years, yes.

Q. And looking at after the Cleaning Sequence 5, you see what appears to be a pristine polypropylene mesh fiber, correct?

A. You do, and it doesn't surprise me because the entire 23-step procedure would take off oxidized polypropylene as well as tissue.

Q. And you also can see the manufacturer's extrusion striations in Patient 42's SEM micrograph, correct?

A. I don't know. It's hard for me to say as I sit here and look at this image. Maybe my eyes

aren't as good as yours.

Q. Comparing -- it looks similar to the picture of the TVT exemplar, right? You can see the striations in each?

A. You do see some what appears to be stripes that are parallel to the fiber axis.

Q. Would those be caused by anything besides the extrusion process?

A. Not that I'm aware of.

Q. And those are both at the same magnification, correct, 200N6 and 208X, Patient 42 in the exemplar, so they are at similar magnifications?

A. I'll take your word for it. I'm having trouble reading that at my age.

Q. So at similar magnifications, you can see -- and the size of the fibers appears to be nearly identical, correct?

A. Yeah, it does look to be similar in terms of the dimensions of the fibers.

Q. In your opinion, how thick, what range -- how thick is the oxidized surface layer on the polypropylene mesh in the explanted mesh?

A. I don't know. I don't know how thick it is.

Q. Is it a range of microns thick?

A. I would not expect it to be microns thick.
Q. Under a micron thick?
A. I -- I'm going to stick with my answer. I simply don't know. I mean, we've never really tried to examine how deep it goes.
Q. Did you try to do any quantification based on the SEM images from Dr. Gido in your own study, how thick that layer was in comparison to the mesh fiber?
A. I did not know.
Q. How thick does the oxidized polypropylene layer need to be to affect the mechanical performance of the mesh?
A. It needs to be thick enough that you see mechanical degradation on the surface, you start to see things like pitting and flaking and cracking. At that point, certainly it's enough.
Q. Is cracking alone enough, or do you need to see pitting or craters?
A. I think cracking alone is a pretty serious flaw and it might be enough.

Another thing you could check is the compliance of the material, what's happened to the modulus of the material.

Q. Did you perform any testing regarding the

modulus of the material?

A. We did not. We had limited material and we chose testing specifically to test to see if oxidative degradation was the -- was the reason the meshes are changing in vivo.

Q. So for Patient 56, for the explant sample on the left in Figure 11, we don't see any surface degradation effects, so that patient's mesh has not been mechanically affected, correct?

A. It's hard to make out to me what we've got in the SEM on the left of Figure 11, because there is something that looks like white flakes in there.

Q. Could that be biologic material?

A. I simply don't know what that material is. I can't just sit here and identify it. I don't know is my answer.

THE VIDEOGRAPHER: Ms. Steele, I have four minutes left on this DVD.

MS. STEELE: Okay. Let's do a quick break.

THE VIDEOGRAPHER: Okay.

MS. STEELE: You can change it now.

THE VIDEOGRAPHER: We're going off the record. The time is approximately 11:04 a.m.

(Recess from 11:04 a.m. until 11:19 a.m.)

THE VIDEOGRAPHER: We're back on the record.

The time is 11:19 a.m., and this begins Media Unit Number 2. Thank you.

BY MS. STEELE:

Q. Dr. Mays, I want to talk about Dr. Thames's FTIR analysis in his study, and look starting with Figure 5 and then Figure 6.

A. Okay.

Q. And looking at Figure 5 first, just to orient, this is the FTIR spectra for Patient 33's explant before any cleaning had been done. Is that right?

A. Yes. It's before cleaning, Patient 33.

Q. And we see that they have highlighted two different regions in the FTIR?

A. Yes, I see that.

Q. And you see -- and they label it protein amide N-H stretching --

A. Yes, I see that.

Q. -- on the far left green circle; is that right?

A. Uh-huh. Yes.

Q. And do you agree with that characterization?

A. I believe that's correct. I don't keep all of these FTIR frequencies in mind. I can certainly agree that the one about 1650 is carbonyl stretching

in an amide bond.

Q. And that is where you would see carbonyl bonds, which is evidence of oxidation on --

A. No. Carbonyl stretching in an amide is at a lower frequency. This is at 1651, roughly.

Q. Uh-huh.

A. And you expect to see carbonyl stretching in a -- something like an ester or carboxylic acid or a ketone. You see that at a higher frequency, somewhere between 1700 and 1740, roughly.

Q. So at which frequency do you look to see evidence of oxidation?

A. You're looking to see a peak generally in the range of about 1730, 1740. That's generally where you see the maximum of the peak.

Q. So on this explanted material that hasn't been cleaned, we see the peak at 1650. So that's evidence of biologic material, not oxidation, correct?

A. I believe that's correct, yes.

Q. And --

A. Although you can't rule out that there is something in there at about 1750, that region we're talking about, 1740, because there is a shoulder on this big peak. So there could be an oxidized -- an

oxidation peak that's there but you simply can't see it because of the intensity of the protein amide carbonyl stretching.

Q. So because of the amount of protein on the surface, it may be hiding the peak --

A. Exactly my point.

Q. -- for the oxidation?

A. Yes. You do see a little shoulder there if you look. Right?

Q. Yeah. And that's -- and do you want to just circle the shoulder you're talking about on the actual exhibit?

A. Absolutely, that little shoulder right there.

Q. Yeah. And Figure 6 we see -- so this is the FTIR spectra for both -- the top is a blue fiber and the bottom is a clear fiber from Patient 33?

A. Yes.

Q. And it shows the progression in the FTIR spectra for both fibers after each cleaning sequence with the identification of which cleaning sequence by -- up in the left-hand corner?

A. Yes, I see that.

Q. The colors of the spectra?

A. I see that.

Q. And we see -- so the royal blue color is for before cleaning. So that's the initial FTIR spectra, similar to what we saw in Figure 5?

A. Yes.

Q. And then we see after each cleaning step the change in the FTIR spectra?

A. Yes, I see that.

Q. And the two green areas are the two areas that Dr. Thames and his colleagues identified as the area where you would see evidence of protein in the FTIR spectra, right?

A. Yes.

Q. And we see with each kind of progression of the cleaning steps, the evidence of protein decrease in the FTIR spectra, correct?

A. Well, you definitely see a decrease in the evidence in all of the clean samples. It's hard for me, as I sit here and look at this, that there is -- these things are offset with one another a little bit.

Q. Uh-huh.

A. So it's hard for me to try to quantify it, but there is a big difference in the amount of protein that's present in the initial sample before cleaning and all of the samples after cleaning.

Q. Okay. Let's look specifically at -- so the royal blue colored line, which is the FTIR for before cleaning.

A. Yes.

Q. And then the purple line, which is the FTIR spectra after the first cleaning sequence, which is after the first six steps, so no ultrasonication has occurred.

A. Yes.

Q. And we see there that there is a drop in the protein levels at both ME peaks between those two steps, significant decrease, correct?

A. Yes, I would agree with that.

Q. And we also see at 1750 -- or no. Let's see. 1730, around 1730 to 1740, where we're looking for the peak of oxidation, after each cleaning step, the FTIR spectra in that region, or cleaning sequence -- the FTIR spectra in that region remains relatively constant, correct?

A. It's hard for me to say with these things kind of offset the way they are, but there is not a huge change in there. It's hard for me to say that, you know, there's less after the final cleaning step as opposed to after the second cleaning step. It's just --

Q. Yeah.

A. It's hard to tell from this. It's hard to quantify from this.

Q. So from after Cleaning 1 through after Cleaning 5, there is not a significant difference between the peak at 1730 to 1740, correct?

A. I simply cannot tell. I simply cannot tell by looking at this, the way these are presented. I'm sorry.

Dr. Thames would have had to have gone in and actually tried to quantify it in some way, just visual inspection with all these FTIR spectra overlay that's --

Q. And so focusing on -- let's just do the top FTIR spectra, and I believe this is the one where you see that slight shoulder that you circled.

A. Yes.

Q. And then we see the lines from each -- after each cleaning sequence at 1730 and 1740 are basically on top of one another, correct?

A. It's -- you know, that's what you were trying to ask me before. I just simply can't say because of the nature of these being overlaid with one another.

When you get an FTIR spectrum, it depends on

how much of the sample that you have within the beam, so to take a bunch of spectra that have been run at different times and try to overlay them without some quantitation and just to sit here and try to look at it and make some quantitative or even qualitative conclusion is very difficult.

Q. Okay. You can set Dr. Thames to the side. And then the next two exhibits, which I believe are 9 and 10, and these are the kind of letter to the editor back-and-forths that were engaged in --

A. Yes.

Q. -- following Dr. Thames' publication of his article.

A. Yes.

Q. And I believe you said you agreed with Dr. Thompson and coauthors' --

A. Well, I --

Q. -- criticisms of Dr. Thames's work?

A. Yeah. I basically agree with them from the standpoint that there's -- had been a lot of prior work to look at polypropylene and what happens to it in vivo, and Dr. Thames just discarded a lot of work by a lot of different people and claimed that only he knew how to clean an explant properly, and so I agree with Thompson, et al., in that regard. They

certainly make that point here.

There is a large body of published literature, you know, describing degradation of polypropylene, that's what they say in this paper, and I agree with them on that point.

I also agree with them on the point that Dr. Thames' procedure is very intense. It's extreme. It's far beyond what's necessary to remove protein and it's into the realm whereas Dr. Thames admits it will basically strip everything off the polypropylene fiber.

Q. And you understand that Dr. Thompson is a attorney for plaintiffs in the mesh litigation?

A. I didn't know that.

Q. If you look at the financial disclaimer/conflicts of interest on the last page of the letter to the editor, we note that Dr. Ostergard, Dr. Guelcher, Dr. Bendavid, Dr. Iakovlev have all given medicolegal consultations and testimony on the plaintiffs' side in mesh litigation cases.

A. I see that's what it says here, yes.

Q. And then Margaret Thompson is actually a obstetrician-gynecologist, but she also is an attorney who represents plaintiffs in this mesh

litigation, correct?

A. I see where it says that, yes.

Q. And then kind of the reply to the response to the article from Dr. Thames, for the most part, just reiterates points from his article and then his interpretation of the literature, but was there anything in particular from this that stood out or you wanted to respond to?

A. You know, he responded and the key thing to me is he's responding at a time when he should have known from his own experimental studies that his extensive 23-step cleaning procedure would remove oxidized polypropylene. He failed to do it, yet he's still defending that procedure, that faulty procedure at this point. That's my take-home message from that.

Q. Okay. And I think just one point on the second page in the right-hand side column. It -- he notes that in an article by Dr. Iakovlev with Dr. Guelcher and Dr. Bendavid, that on the -- the flaked matter on the polypropylene fibers was only up to five-thousandths of a millimeter thick even more than 10 years after implantation.

A. I see where it says that.

Q. And if there is an oxidized -- if you accept

that the oxidative process is happening and the surface layer is oxidized polypropylene, will a surface layer of oxidized polypropylene that is up to five-thousandths of a millimeter thick affect the mechanical performance of the polypropylene mesh?

A. I simply don't know, and we touched on this earlier today. You know, you would have to do some testing to see when you -- you'd have to first test how thick the layer is and correlate that with some mechanical testing, such as compliance or modulus. I think that would be how you would tell. I can't just sit here and tell you. I'm sorry. I don't know.

Q. Okay. And then turning back to your PowerPoint, which is Exhibit 13 that you produced today.

A. Yes.

Q. For the most part, this summarizes your testing and then highlights certain articles from the published literature regarding the testing of explanted polypropylene mesh for oxidative degradation, right?

A. That's absolutely correct. What I would say is there is really nothing in there that's not in my report.

Q. Okay. Can you just -- what was the circumstances under which you gave this presentation?

A. Yeah. I've known the folks at Tosoh Bioscience for some years because we use GPC a lot in my research. I'm considered to be something of an expert in the area, and they have started to have an annual or maybe biannual meeting on GPC and they invited me to give the plenary lecture. I think they had gotten word that I was retiring and they said talk about anything you want to. I said, well, how about high-temperature GPC and kind of a biomaterials application, and they said sure. And so I gave that presentation there as an invited talk.

Q. And that was at Tosoh Biosciences?

A. Tosoh Bioscience sponsored it. The meeting was held in Atlanta. I can't remember the hotel it was at.

Q. Okay.

A. But it was a meeting in Atlanta in July of last year.

Q. And was it a -- like what was -- was there a title for the meeting? Was it a certain organization?

A. Yeah. It was called GPC2017, which is what you will see right --

Q. Oh.

A. Yeah, that's what they called it. So you could -- you could look up on the Internet, I'm sure, and still find some records of it, or --

Q. My invite must have gotten lost in the mail.

I just want to ask you about a couple of statements that you have in the PowerPoint. We just have the one copy, so I'm going to try to share with you.

A. Sure.

Q. And so this is talking about your studies that you did as part of your analysis of the 11 Boston Scientific explants, right?

A. Yes.

Q. And we see the first one says used FTIR to check for oxidation and it was complicated by biological material; is that right?

A. Yes. And what I mean by that statement is these explants were in formalin, and so we know that there is fixated tissue on there, so one has to either use a technique that allows one to look around that fixated biological tissue, such as SEM EDS, which is what Gido did with all but one of the

materials, or you have to use a cleaning procedure to get the material off if you're going to use something like FTIR, which looks at a larger region of the material.

Q. And for bullet -- the next bullet point says: Used SEM/EDS to check for oxidation and monitor mesh fiber degradation.

A. Yes.

Q. Complicated by biological material, correct?

A. Again, you can look at regions on the surface of the fiber and you may be looking at a region where there is biological material, or you look at another area and you may be looking at an area where there is not biological material, or a minimal amount of it.

The key point of that study, the key finding in that study was we could find regions on the fibers which showed no nitrogen or only trace amounts of nitrogen, but had substantial amounts of oxygen. If there is equal amounts of nitrogen and oxygen present, that's characteristics of an amide bond, so that means protein, but if you're seeing oxygen and you're not seeing appreciable amount of nitrogen, that's an indicator of oxidation occurring in the material, because polypropylene doesn't have

oxygen in it when it begins.

Q. And also in here you state no amide bands were seen in FTIR but FTIR and SEM/EDS cannot completely exclude fatty acid plasticization, correct?

A. Yes, that's correct.

Q. That's what it states?

A. That's what it states.

Q. And that's because fatty acids show up in the same -- the FTIR spectra are present at the same location as you would see evidence of oxidation; is that correct?

A. Well, fatty acids contain carbon and oxygen, just like oxidized polypropylene contains carbon and oxygen, so you might confuse those for one another, and so that was really the main point of this study. And I think the key thing -- at the time we did the work, there were two schools of thought on why -- and Clave admits this -- why polypropylene was not inert in the body. One, it's interacting in some way with these fatty acids and it's a plasticizing effect, or the hypothesis that oxidative degradation is occurring.

So our GPC experiments show clearly the reduction in molecular weight. That's not something

that fatty acid plasticization can do, but it's entirely consistent with a known mechanism of oxidative degradation of polypropylene.

Q. And as we discussed earlier, your study did not correlate lengths of implant time with greater reduction in molecular weight, correct?

A. We were not able to do that with the limited number of samples that we had. We only had four samples where we had enough material that we could do the GPC experiment in triplicate. We insisted on showing the reproducibility and reliability of the data. I would love to have more materials that had been explanted after varying periods of time, but we simply used the four samples that we had.

I think we might see more of a correlation if we had more samples. I would expect to see, if we had more samples, I would expect to see more degradation after longer periods of time, because it's known that this foreign body response doesn't stop, it continues to take place.

Q. And you aren't able, based on your expertise, to correlate how much reduction in molecular weight is necessary to result in a clinical complication for a patient, correct?

A. I am not able to do that, you're correct.

Q. And a few more points and then I think we're almost done.

For Dr. Spiegelberg's test method, do you know how many steps are in Dr. Spiegelberg's test method?

MR. PERDUE: In cleaning or testing?

Q. His cleaning method for his testing. I'll restate the question so it's clean.

A. Okay.

MR. PERDUE: I'm sorry.

MS. STEELE: You're good. Yeah, we're good.

BY MS. STEELE:

Q. Do you know how many steps are in the cleaning method used by Dr. Spiegelberg in his testing in this litigation?

A. I saw some reports from Spiegelberg but I haven't looked at them recently. I seem to recall at one point in time that he put the material in concentrated KOH and boiled it there for an extended period, but -- that made an impression on me, but I don't remember what else he might have done during the cleaning. I'd be happy to review it and comment but I just can't, as I sit here, recall.

Q. In the expert report you served in June of 2018 you did not include any criticisms of

Dr. Spiegelberg's testing and results, correct?

A. I did not, to the best of my knowledge, include anything there. It doesn't mean I'm not critical of them.

Q. And you -- and we looked. Your first report in the Boston Scientific pelvic mesh litigation was in 2013, correct?

A. Yes.

Q. So that was about five years ago?

A. Yes.

Q. And are you aware that doctors still widely support the use of polypropylene midurethral slings for the treatment of stress urinary incontinence?

MR. PERDUE: Form.

A. That wouldn't surprise me at all. They make a lot of money putting these meshes into women.

Q. So your opinion is that doctors support these midurethral slings because they are making a lot of money putting them in?

A. I would certainly suspect there is a correlation there.

Q. So any doctor who is implanting a medical device is doing so because they are making a lot of money doing it?

MR. PERDUE: Form.

A. Well, doctors are out to try to relieve pain and symptoms, problems that people have, they are out to treat it, but certainly the surgeons that implant these materials, those surgeries aren't cheap.

Q. Are Burch procedures cheap?

A. No, none of those procedures are cheap.

MS. STEELE: I think that's all the questions I have.

MR. PERDUE: We'll reserve ours. Thank you very much.

THE WITNESS: Thank you.

MS. STEELE: Thank you.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: This concludes the deposition. The time is approximately 11:44 a.m.

(Whereupon, the deposition concluded at 11:44 a.m.)

C E R T I F I C A T E

I, SUSAN D. WASILEWSKI, Registered Professional Reporter, Certified Realtime Reporter, Certified Realtime Captioner, Certified Manager of Reporting Services, Florida Professional Reporter, and Certified Court Reporter (New Jersey), do hereby certify that, pursuant to notice, the deposition of JIMMY MAYS, Ph.D., was duly taken on Thursday, August 16, 2018, at 9:08 a.m. before me.

The said JIMMY MAYS, Ph.D., was duly sworn by me according to law to tell the truth, the whole truth and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness, and that a review of the transcript was not requested.

_____

Susan D. Wasilewski, RPR, CRR, CRC, CMRS, FPR, CCR(NJ)

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LAWYER'S NOTES

PAGE	LINE	